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| APPLICATION NO.       | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|---------------------|------------------|
| 09/674,337            | 07/26/2001  | Satoshi Mori         | 55107               | 5232             |
| 21874                 | 7590        | 11/18/2004           |                     |                  |
| EDWARDS & ANGELL, LLP |             |                      |                     |                  |
| P.O. BOX 55874        |             |                      |                     |                  |
| BOSTON, MA 02205      |             |                      |                     |                  |

|                     |
|---------------------|
| EXAMINER            |
| FRONDA, CHRISTIAN L |

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
| 1652     |              |

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/674,337

**Applicant(s)**

MORI ET AL.

**Examiner**

Christian L Fronda

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,6 and 8-26 is/are pending in the application.
- 4a) Of the above claim(s) 8-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Claims 1-3 and 6 are under consideration in this Office Action.
2. The paper copy and computer readable form (CRF) of the Sequence Listing filed on 08/05/2004 have been received and have been processed by the Scientific and Technical Information Center (STIC).

#### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 1-3 and 6 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1; does not reasonably provide enablement for a nicotianamine synthase having 50% identity to SEQ ID NO: 1 and comprising at least one of amino acid sequences (1)-(6).

Applicants' arguments filed 08/05/2004 have been fully considered but they are not persuasive. Applicants' position is that the amended claim 1 recites a polypeptide having more than 50% identity with SEQ ID NO: 1 and comprising 101 conserved amino acid residues. The Examiner disagrees for the reasons of record as supplemented below.

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed nicotianamine synthase having more than 50% identity to SEQ ID NO: 1 and comprising 101 conserved amino acid residues as recited in claim 1 is undue. SEQ ID NO: 1 is disclosed by the specification as an amino acid sequence of 328 amino acid residues. The claims require at least 50% of SEQ ID NO: 1 to be altered, where at least 164 amino acid residues are changed (deletion, insertion, substitution, or combinations thereof) in SEQ ID NO: 1, and of those 164 amino acid residues that are to be changed, 101 amino acids must be conserved as recited in claim 1. However, there remains 63 amino acid residues that are to be altered.

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One of ordinary skill in the art would have to screen and search for proteins having the changes in the amino acid sequence and then determine by enzymatic assays whether the protein has nicotianamine synthase activity. Such screening and searching is outside the scope of routine experimentation. Teaching regarding searching or screening for the claimed invention is not teaching for making the claimed nicotianamine synthase. Limiting the claims to recite the specific amino acid sequences of (1)-(6) does not overcome the rejection since no more than 32 amino acid residues out of a total of 328 amino acid residues of SEQ ID NO: 1 are accounted for.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific 63 amino acid residues which can be changed without inactivating enzyme activity. Without such a guidance, the amount of experimentation left to those skilled in the art to make the invention is undue and well outside of routine experimentation.

### *Conclusion*

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

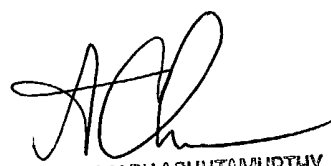
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

8. Information regarding the status of an application may be obtained from the Patent

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Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



PONNATHAPU ACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600